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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/686,499	10/11/2000	Roy Curtiss III	3116-1192	5788

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EXAMINER

SHAHNAN SHAH, KHATOL S

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 08/27/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding:

Office Action Summary

Application No.

09/686,499

Applicant(s)

CURTISS, ROY

Examiner

Khatol S Shahnan-Shah

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22,45 and 46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22,45 and 46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 17.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

1. Applicant's response received 5/12/2003, paper 18 is acknowledged.
2. Applicant's Information Disclosure Statement received 5/12/2003, paper 17 is acknowledged. The references have been considered by the examiner.
3. Currently claims 1-22 and 45-46 are pending and under consideration.

Prior Citations of Title 35 Sections

4. The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior office action.

Prior Citations of References

5. The references cited or used as prior art in support of one or more rejections in the instant office action have been previously cited and made of record. No form PTO-892 has been submitted with this office action.

Rejections Maintained

8. Rejection of claims 1, 2, 8- 13, 16 and 21-22 under 35 U.S.C. 102 (e) made in paragraph 9 of the office action mailed on 1/29/2002 (paper number 11) is maintained.

The rejection was as stated below:

Claims 1, 2, 8- 13, 16 and 21-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Portnoy et al. (US Patent 6,004,815).

Claims are drawn to an attenuated derivative of a pathogenic microorganism, recombinant vector and a gene operably linked to an eukaryotic promoter.

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Portnoy et al. disclose an attenuated derivative of a pathogenic microorganism (*E.coli*) (see abstract, table 1 and claims 1-6), plasmid vectors (column 8, table 2) and gene operably linked to an eukaryotic promoter (CMV) (see column 3). They teach *E. coli* deficient in the production of DAP (see column 16) and a recombinant complementing gene on a vector (plasmid pWR 100 from *Shigella flexneri* (column 16). The prior art discloses the claimed products.

Since the office does not have the facilities for examining and comparing applicant's products with the products of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed products and the products of the prior art (i. e., that the products of prior art does not possess the same material structure and functional characteristics of the claimed products). See In re Best, 562 F.2 d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant's arguments filed 5/12/2003 have been fully considered but they are not persuasive.

Applicant argues that Portnoy et al. do not teach a vector with a recombinant complementary gene. Applicant argues " The bacteria shown in Table 1 and described in the other parts of Portnoy are merely attenuated and do not possess an non functional native chromosomal essential gene." Applicant further argues that the plasmids in Table 2 in Portnoy et al. do not carry a complementary essential gene.

It is the examiner's position to bring applicant's attention to the fact that Portnoy et al. teach an essential gene that encodes a function that is required for viability as admitted by the applicant in the response. DAP is required for viability of the microorganism. Therefore Portnoy et al. teach an essential gene that encodes a function that is required for viability. In regard to the recombinant complementing gene on an extra chromosomal vector the applicant attention is directed to Table 2. The plasmid pDP3615 carrying strain MC4100 (DE3) an RNA polymerase essential gene. Portnoy also recite in column 3, lines 51-55 " In particular, the polynucleotide

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may encode a transcription factor, whereby expression of the transcription factor in the target cell provides activation or de-activation of targeted gene expression in the target cell. Thus Portnoy reference teaches each element of the claimed invention.

9. Rejection of claims 1-7, 12-20 and 45-46 under 35 U.S.C. 102 (e) made in paragraph 8 of the office action mailed on 12/16/2002 (paper number 15) is maintained.

The rejection was as stated below:

Claims 1-7, 12-20 and 45-46 are rejected under 35 U.S.C. 102(e) as being anticipated by Curtiss III et al., (US Patents Number 6024961) Prior art already made of record.

Claims are drawn to an attenuated derivative of a pathogenic microorganism (Enterobacteriaceae) comprising a non functional native essential gene and a recombinant complementing gene on a vector (plasmid) encoding a replacement for an essential enzyme. And the desired gene product is a bacterial antigen. The above product was achieved by the use of the balanced- lethal host-vector system.

Curtiss III et al. (US Patent No. 6024961) disclose an avirulent immunogenic strain of *Salmonella enterica* serotype Typhi having a mutation in one or more genes comprising of pab, pur, aro, asd, dap, nadA, pncB, galE, pmi, fur, rpsL, ompR, htrA, hemA, cdt, cya, crp, phoP, phoQ, rfc, poxA, galU, or a combination thereof. (See claims, figures specially figure 7 and abstract) They also teach a recombinant gene encoding the desired gene product (see column 11). They disclose bacterial antigens (column 11). They also disclose recombinant vectors (example 2, column 28) and desired gene product cytokine (columns 10 and 11). The prior art discloses the claimed products.

Since the office does not have the facilities for examining and comparing applicant's

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products with the products of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed products and the products of the prior art (i. e., that the products of prior art does not possess the same material structure and functional characteristics of the claimed products). See In re Best, 562 F.2 d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant's arguments filed 5/12/2003 have been fully considered but they are not persuasive.

Applicant mainly argues embodiments of US Patent No 5,672,345 and do not argue the prior art US patent No. 6,024,961 which the anticipation is based upon. Applicant further argues the examples of the instant application. Applicant also argues newer techniques of generating defined deletion mutations.

It is the examiner's position that it appears that the applicant is arguing limitations that are not in the claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Conclusion

10. Claims 1-22 and 45-46 stand rejected.

11. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**


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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol S Shahnan-Shah whose telephone number is (703) 308-8896. The examiner can normally be reached on 7:30am-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith can be reached on (703) 308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.


Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

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August 19, 2003


RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER